

MINUTES OF MEETING
HEALTH SERVICES COUNCIL

DATE: 13 December 2011

TIME: 2:30 PM

LOCATION: Conference Room 401

ATTENDANCE:

| Name | Present | Absent | Excused |
|--------------------------------|---------|--------|---------|
| Victoria Almeida, Esq. (Chair) | X | | |
| Raymond C. Coia, Esq. | X | | |
| John X. Donahue | | | X |
| Joseph L. Dowling, MD | X | | |
| John W. Flynn | X | | |
| Wallace Gernt | X | | |
| Maria R. Gil (Secretary) | X | | |
| Catherine E. Graziano, RN, PhD | | | X |
| Robert Hamel, RN | X | | |
| Theresa Jeremiah | X | | |
| Amy Lapierre | X | | |
| Steven Lonardo | | | X |
| Thomas M. Madden, Esq. | X | | |
| Daniel Orgel, MPA | X | | |
| Denise Panichas | | | X |
| Robert Ricci | | X | |
| Reverend Shire (Vice-Chair) | X | | |
| Robert Whiteside | | X | |

Staff: Valentina D. Adamova, MBA, Michael K. Dexter, MPA, Joseph G. Miller, Esq.

Public: (Attached)

1. Call to Order, Approval of Minutes, Conflict of Interest Forms and Time Extension for the Minutes Availability.

The meeting was called to order at 2:37 PM. Minutes of the Health Services Council meeting of 25 October 2011 were adopted as submitted. The Chair noted that conflict of interest forms are available to any member who may have a conflict. A motion was made, seconded and passed by a vote of eleven in favor and none opposed (11-0) that the availability of the minutes for this meeting be extended beyond the time frame provided for under the Open Meetings Act. Those members voting in favor were: Almeida, Coia, Dowling, Flynn, Gernt, Hamel, Jeremiah, Lapierre, Madden, Orgel, Shire.

2. General Order of Business

The next item on the agenda was the *Report of the Committee of the Health Services Council on the applications of **Home Care & Hospice of New England, Inc. Rhode Island, Inc.** for change in effective control of Home & Hospice Care of Rhode Island, Inc. and Visiting Nurse Service of Greater Rhode Island, Inc.* Staff summarized the applications and deliberations of the Committee on this matter.

A motion was made by Mr. Gernt, seconded by Mr. Madden and Reverend Shire and passed by a vote of twelve in favor and none opposed (12-0) to recommend that the applications be approved subject to the conditions of approval. Those members voting in favor included: Almeida, Coia, Dowling, Flynn, Gernt, Gil, Hamel, Jeremiah, Lapierre, Madden, Orgel, Shire.

The next item on the agenda was the *Addendum II to the report of the Health Services Council on the Certificate of Need application of **Miriam Hospital** [Lifespan Corporation] to construct three floors to house medical/surgical nursing units, upgrade the Emergency Department, and consolidate and upgrade diagnostic and patient treatment area.* Staff summarized the change order request and deliberations of the Committee on this matter.

A motion was made by Mr. Coia, seconded by Ms. Jeremiah and passed by a vote of twelve in favor and none opposed (12-0) to recommend that the change order request be approved subject to the conditions of approval. Those members voting in favor included: Almeida, Coia, Dowling, Flynn, Gernt, Gil, Hamel, Jeremiah, Lapierre, Madden, Orgel, Shire.

The next item on the agenda was the *Addendum to the report of the Health Services Council on the application of **American Senior Living Communities II, LLC** d/b/a American Senior Living Communities RI II, LLC for change in effective control of Hebert's Nursing Home, Inc.* Staff summarized the change order request and deliberations of the Committee on this matter.

A motion was made by Mr. Gernt, seconded by Mr. Coia and passed by a vote of twelve in favor and none opposed (12-0) to recommend that the change order request be approved subject to the conditions of approval. Those members voting in favor included: Almeida, Coia, Dowling, Flynn, Gernt, Gil, Hamel, Jeremiah, Lapierre, Madden, Orgel, Shire.

The next item on the agenda was the *Report of the Committee of the Health Services Council on the applications of **FC-GEN Investment, LLC** for change in effective control of: Coventry Skilled Nursing and Rehabilitation; Greenville Skilled Nursing and Rehabilitation; Pawtucket Skilled Nursing and Rehabilitation; Warren Skilled Nursing and Rehabilitation.* Staff summarized the applications and deliberations of the Committee on this matter.

Mr. Quinn, representing 1199/SEIU, and other members of the union noted their concerns about the operations of the two nursing facilities (Greenville and Pawtucket).

A motion was made by Mr. Gernt, seconded by Dr. Dowling and Reverend Shire and passed by a vote of eleven in favor and one opposed (11-1) to recommend that the applications be approved subject to the conditions of approval. Those members voting in favor included: Almeida, Coia, Dowling, Flynn, Gernt, Gil, Hamel, Lapierre, Madden, Orgel, Shire. The members voting opposed: Jeremiah.

The next item on the agenda was the *Report of the Committee of the Health Services Council on Radiation Oncology Associates, Inc.'s change order request to prior Certificate of Need applications to operate three linear accelerators*. Staff summarized the application and deliberations of the Committee on this matter.

Michael K. Dexter, staff to the Council, introduced the application and gave a brief description of the project and identified applicable documents.

Dr. Oldenburg, President of Radiation Oncology Associates, Inc. (ROA), stated that a previous change was granted to ROA for partnership with Vantage Oncology which came in as a capital partner and a manager of the center. He noted that this change order request was a long effort over years to find a way to integrate and work together to support the mission of Pratt Radiation Oncology Associates, Inc. (PRATT). He said that this is a transfer of ownership (24.5%), from ROA to PRATT. He noted that no new services are proposed to be provided and no equipment replaced.

Dr. Wazer addressed several points in the letter of 13 December 2011 from Mr. Devereaux, legal counsel to Radiation Therapy Services, Inc. d/b/a 21st Century Oncology. He stated the following in response to point #5 in the letter. He said that he serves as the Medical Director at Radiosurgery Center of Rhode Island (RCRI) at the pleasure of Chuck Mahoney, President of RCRI. Mr. Mahoney sees no conflict whatsoever and in fact fully recognizes that this proposed transaction is part of his, Dr. Wazer's, responsibility as a chairman at the department at Brown University (Brown). He said that he has broad responsibility to look at the development of radiation oncology at Brown within the entire academic system as well as within the Lifespan system. This proposal is viewed as not in any way in conflict with his multiple responsibilities and multiple hats that he wears.

Dr. Wazer stated the following in response to point #9 of the letter and the suggestion that he threatened the viability of RCRI. He stated that given the fact that PRATT accounts for 85% of patient treatments at RCRI, RTSI accounts for 15% and that volume is despite a commitment by RTSI that they would provide 40% of patient volume at RCRI. Dr. Wazer further stated that the viability of RCRI is threatened by RTSI's failure to meet their contractual obligations.

Dr. Wazer stated the following in response to point #11 of the letter regarding RTSI's statement that RTSI can provide the same type of academic and research collaboration, that is being pursued with ROA, at no cost. He stated that RTSI's doctors are not Brown faculty and have been extended a courtesy appointment by him as adjunct faculty in an effort to encourage and engage them in academic activities. He said that so far they have declined to do so. He noted that RTSI's doctors all practice at hospitals that are not affiliated with Brown and as such by Brown's rules they are not eligible for full Brown faculty participation. He further stated, that in their

current practice situation, RTSI's doctors do not perform any research, they do not publish papers, they perform no teaching, they enroll no patients in clinical trials, and they do not participate in the community collaborative oncology effort that is sponsored through the Brown's oncology group. He said that there have been repeated requests of RTSI to contribute financial support for research and education, to participate in clinical trials, to participate in teaching, and to-date RTSI has refused. He noted that he would welcome their participation but that this is a new-found passion of RTSI. He said that he would like to contrast that with the relationship of ROA with Brown over a period of 40 years. He stated that ROA has been on Brown's faculty for 40 years, actively offer clinical trial participation in their office, and actively participate in educational programs at The Miriam Hospital and Women & Infants Hospital. He further noted that ROA's doctors actively teach at Brown and they participate in the Brown's oncology program. He said that RTSI has put forward false issues.

Dr. Oldenburg stated the following in response to points #6 and #10 of the letter. He stated that the original three CONs issue to ROA were for cobalt machines and received one-for-one exchanges. He said that the technology for radiation is not static; and that every machine that you buy currently is capable of doing stereotactic but it's not capable of being a CyberKnife, which is a special form of stereotactic treatment. He noted examples of other one-for-one replacements that have stereotactic capabilities. He stated that the technology is what the technology is and you cannot buy old technology. He likened it to an example of buying a Sony walkman rather than an MP3 player. He stated that ROA is providing state-of-art treatments. He noted that practice scope changes too and that stereotactic used to be considered specialty non-conventional treatment and now is considered a standard practice for inoperable stage one lung cancer. He further noted that every radiotherapy department has to be able to offer at least the ability to treat stage one lung cancer. He said that it doesn't mean that ROA's equipment provides all the services of a CyberKnife.

Dr. Oldenburg additionally said that the letter implied that ROA lied in their request for one-for-one replacement. He read from the one-for-one application, which was included Tab A of Mr. Devereaux's 13 December 2011 letter, where it describes the capabilities of the machine to include stereotactic capabilities.

Mr. Devereaux, legal counsel to RTSI, said that the Council needs to scrutinize this request because it raises a number of significant questions that the Council has the authority and duty to look at. He said that one of issues raised is a potential significant conflict of interest. He said Dr. Wazer was the lead presenter for RCRI. He noted that a one-for-one replacement was not permitted in that instance and a certificate of need review was required. He said that the proposed investment is in a competing entity and noted a non-compete clause (in the Amended and Restated Operating Agreement of Providence Radiation Oncology Partners, LLC). He stressed the issue of competition. He further noted that ROA's website identifies stereotactic radiosurgery capabilities (a copy of which was included in Tab C of Mr. Devereaux's 13 December 2011 letter). He said that this a blatant potential conflict of interest and something that the Council needs to be concerned about when looking at need and affordability and how the community works in this particular state.

Dr. Shafman, NE Regional Director for RTSI, stated that there is no difference between SBRT and SRS performed on a linear accelerator or CyberKnife. He said that the treatments, patients, tumors, codes and payments are the same. He disagreed with Dr. Wazer's statements about research capabilities of RTSI's doctors, their teaching responsibilities and clinical trial participation. He said that he was never asked to be part of any research or teaching at Brown.

Mr. Devereaux cited examples of CON requirements rather than one-for-one replacements. He noted that ROA was able to achieve one-for-one replacements.

Mr. Mercurio, representative of RTSI, said that CyberKnife was the first project he was involved in where there was collaboration rather than competition. He also noted the modernization of Roger Williams Medical Center's (RWMC) radiology department. He said that in his experience a certificate of need is required to provide stereotactic radiosurgery.

Mr. Devereaux stated that he is advocating that Council give careful scrutiny to this change order request. He noted that this is not just a simple business transaction. He said that the Council has obligations and duties to look at what is best overall for Rhode Island's healthcare community. He said that he would submit that under the circumstances here, there is a potential conflict of interest that could not bode well for the Rhode Island healthcare community. He said that when he looked at the financials it seemed to him that it was not a great deal.

Mr. Dexter, staff to the Council, noted that the one-for-one requests are administratively reviewed by the state agency and not by the Council. He noted that one-for-one request of RWMC to replace a linear accelerator with a CyberKnife was granted (but not implemented). He clarified however it was the joint ventures (RWRT and RCRI) that did not own medical equipment that could not get one-for-one replacement and hence needed a CON. He noted that the state agency does not want to inhibit the gold standard of practice and does not require CON every time a piece of equipment or a type of therapy is improved if it stays within the same thread of clinical application, function and purpose. He cited as an example the permission of one-for-one upgrade from a PET to a PET/CT unit.

A question concerning the application of the Stark law was raised and was answered by Mr. Chase-Lubitz, legal counsel to PRATT, who noted that there is an exception under the law for radiation oncology ('consultation exception') and described it in detail. Ms. Warren, legal counsel to ROA, noted that there are no referrals between these parties. To address the issue of conflict of interest, she said that it is medical oncologist who make referrals. She further noted that Dr. Wazer is the Medical Director at RCRI at the pleasure of Mr. Mahoney and will continue to serve. She further noted that it is unclear why the former one-for-one replacement and CON issues are being discussed, since these same issues were raised during the previous change order request in 2007. She discussed the previous change order review process which included challenges by the same individuals and resulted in a declaratory ruling regarding the CON issue. She stated that ultimately the ROA change order request was approved.

Following all the presentations, discussions, questions by Council members and consideration thereof, a motion was made to approve the change order request by Mr. Madden. The motion was seconded by Rev. Shire. The Council further discussed the change order request, and Mr.

Coia requested that Mr. Mercurio clarify his comments. Mr. Mercurio as part of his statement said that it is RTSI's position that the Council may be allowing a physician to buy into an entity that may have a linear accelerator that's being allowed to perform functions that is not properly been given the regulatory authority by the state agency by going through a CON in order for it to be able to do stereotactic radiosurgery. Ms. Warren stated that this happened in 2009 and is not now before the Council and staff explained the reason why one-for-one replacement was permitted. She stated that what you have before you is a change in membership interest. She said that this is a simple change order request. Dr. Oldenburg said that in 2011 only 60 out of 19,500 radiation treatments were stereotactic treatments and that any machine you buy today is capable of delivering stereotactic treatments. Mr. Devereaux said that if there is any question that the authority was not correct at the time the one-for-one replacement that he disagrees that it should not be looked at by the Council. Mr. Gernt called the question. The motion passed by a vote of eight in favor, two opposed and two member abstaining (8-2-2), to recommended that the change order request be approved subject to the conditions of approval.

3. Adjournment

There being no further business, the meeting was adjourned at 4:40 PM.

Respectfully submitted,

Valentina D. Adamova, MBA
(Acting) Chief Health Program Evaluator